

THAT WHICH IS CLAIMED

1. A stabilized pharmaceutical composition comprising fibroblast growth factor (FGF) or variant thereof and at least one reducing agent in an amount sufficient to inhibit oxidation of said FGF or variant thereof and wherein cysteine residues in said growth factor need to be maintained in a reduced state.
2. The composition of claim 1, wherein said FGF lacks any disulfide bonds.
- 10 3. The composition of claim 1, wherein said composition is a liquid formulation.
- 15 4. The composition of claim 1, wherein said composition is a lyophilized formulation.
5. The composition of claim 1, wherein said FGF is FGF-2.
- 20 6. The composition of claim 5, wherein said FGF-2 includes any biologically active fragment or variant of FGF-2.
7. The composition of claim 5, wherein said FGF-2 is recombinant FGF-2.
- 25 8. The composition of claim 1, wherein said reducing agent is a thiol derivative.
9. The composition of claim 8, wherein said thiol derivative is selected from the group consisting of dithiothreitol (DTT), n-acetyl-cysteine, or a combination thereof.

10. The composition of claim 9, wherein said composition has a hemolytic potential of less than about 10%.

11. The composition of claim 1, wherein said composition has a pH within 5 the range of about pH 3.0 to about pH 7.5.

12. The composition of claim 11, wherein said composition has a pH within the range of about pH 5.5 to about pH 6.5.

10 13. The composition of claim 9, wherein said DTT is present at a concentration of about 0.1 mM to about 10 mM.

14. The composition of claim 9, wherein said n-acetyl-cysteine is present at a concentration of about 0.5%.

15 15. A method for increasing stability of FGF or variant thereof in a pharmaceutical composition, said method comprising incorporating into said composition a reducing agent in an amount sufficient to inhibit oxidation of said FGF or variant thereof.

20 16. The method of claim 15, wherein said FGF is FGF-2.

17. The method of claim 16, wherein said FGF-2 is recombinant FGF-2.

25 18. The method of claim 15, wherein said reducing agent is a thiol derivative.

19. The method of claim 18, wherein said thiol derivative is selected from the group consisting of dithiothreitol (DTT), n-acetyl-cysteine, or a combination thereof.

5 20. The method of claim 15, wherein said composition has a pH of about pH 3.0 to about pH 7.5.

21. The method of claim 20, wherein said composition has a pH of about pH 5.5 to about pH 6.5.

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22. A method for increasing storage stability of a pharmaceutical composition comprising FGF or variant thereof, where said FGF or variant thereof becomes oxidized during storage, said method comprising incorporating into said composition a reducing agent in an amount sufficient to inhibit oxidation of said FGF or 15 variant thereof.